

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Device Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

DMB
Display Date 5-22-02 @ 3:52 PM
Publication Date 5-28-02
Certifier R LEDESMA

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Region (SWR), Dallas District Office, in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled "Medical Device Workshop." This public workshop is intended to provide information about FDA's medical device quality systems regulation (QSR) to regulated industry and, in particular, to small businesses.

Date and Time: The public workshop will be held on July 19, 2002, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Texas A&M University Health Science Center, Baylor College of Dentistry, 3302 Gaston Ave., sixth floor, Dallas, TX 75246. Directions to the facility are available on the Internet at the Texas A&M University Health Science Center, Baylor College of Dentistry at <http://www.tambcd.edu/>.

Contact: David Arvelo or Sue Thomason, Southwest Regional Office (HFR-SW16), Food and Drug Administration, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247, 214-655-8100, ext. 130 or 128, FAX 214-655-8114, or e-mail: oraswrsbr@ora.fda.gov.

Registration: Preregistration by June 7, 2002, is encouraged. FMDIC has a \$150 preregistration fee. To preregister, please complete the form provided in this document and send it along with a check or money order for \$150 payable to the FMDIC, c/o FDA/SWR/Small Business Representative, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247. As an alternative, the registration form can also be obtained on the Internet at <http://www.geocities.com/Eureka/Suite/3316/>. Seats
ora0211

N.M.1

are limited. Please submit registration forms as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive written confirmation. Registration will close once the course is filled. Onsite registration will be done on a space-available basis on the day of the public workshop beginning at 8:30 a.m. The cost of registration at the site is \$175, payable to the FMDIC. If you need special accommodations due to a disability, please contact David Arvelo or Sue Thomason at least 7 days in advance.

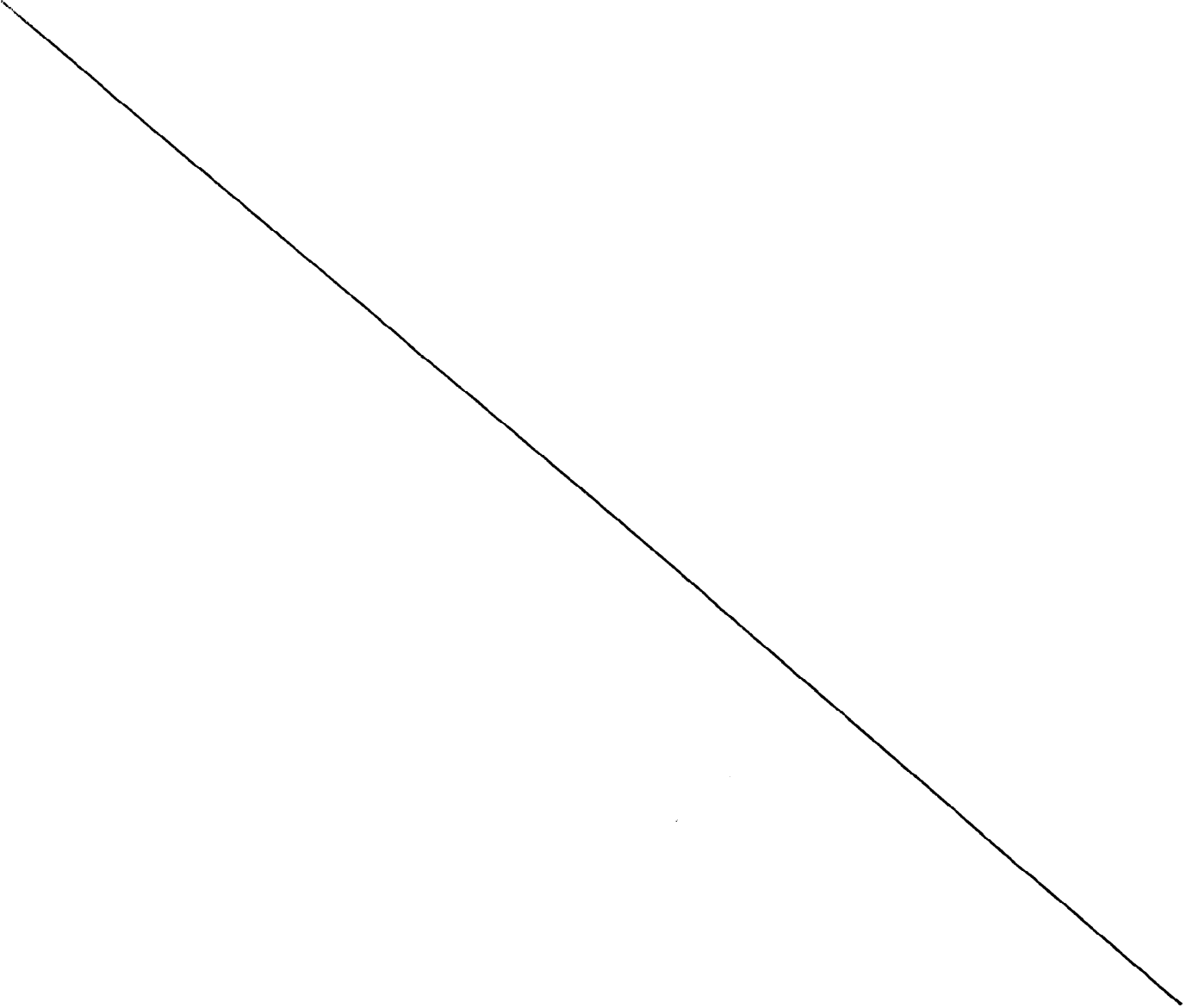
The following information is requested for registration purposes:

Name:	<hr/>		
Company:	<hr/>		
Mailing address:	<hr/>		
City:	State:	Zip code:	
<hr/>	<hr/>	<hr/>	
Phone:	FAX:	<hr/>	
<hr/>	<hr/>	<hr/>	
E-mail:	<hr/>		

SUPPLEMENTARY INFORMATION: The workshop is being held in response to the interest that small medical device manufacturers in the Dallas District area have expressed in the topics that will be addressed at the workshop. FMDIC and FDA will present this workshop to help achieve objectives set forth in section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This workshop is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), because it is an outreach activity by a government agency directed at small businesses.

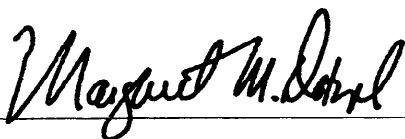
The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the QSR (21 CFR part 820). Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Analysis of FDA 483s, (2) analysis of FDA warning letters, (3) how corrective and preventive actions (CAPA) relates to QSR and the Quality System Inspection Technique, (4) designing and implementing a CAPA system, and (5) the role of complaint files in a CAPA system.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested in writing from the Freedom of Information



Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, starting approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: 5-22-02
May 22, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

